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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,515	01/15/2004	Luca Brambilla	2027.633082/RFE	7827

7590 08/24/2004
Raymund F. Eich, Ph.D.
WILLIAMS, MORGAN & AMERSON, P.C.
Suite 1100
10333 Richmond
Houston, TX 77042

EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,515

Applicant(s)

BRAMBILLA ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 10/130061.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/30/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

This Office Action is in response to a Preliminary Amendment filed 1/15/04.

Claims 8 and 9 have been cancelled. Claims 1-7 and 10 have been amended. Claims 1-7 and 10 are pending in this application.

Information Disclosure Statement

An IDS filed 5/30/04 has been identified and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Claim Objections

Claim 2 is objected to because of the following informalities: it contains the following abbreviation ARS, please define. Claim 7 is objected to because it contains the following abbreviations ADH1, GAL and CYC1, please define. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite in that the metes and bounds of "and/or nucleic acids" are unclear. If the transformation is done in the absence of nucleic acids, it is unclear how the cells are transformed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection.**

Claim 1 has been amended to recite "recovering the protein". Support for the limitation that the protein is recovered has not been found in the specification and the applicant has not indicated where support exists for the inclusion of these limitations to the claims. According to the specification, *Z. bailii* cells are transformed with plasmids encoding β -gal. Expression of β -gal was assayed from the protein extract (example 4). Therefore, the specification teaches expression of proteins in *Z. bailii* but not, specifically, production and the recovery of the expressed protein.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by

Gilbert et al (US 2002/0034805; see entire document).

Gilbert et al. teach expression of fusion proteins that find use in the enzymatic synthesis of oligosaccharides (see e.g. paragraph 0055. Expression vectors encoding said proteins are transformed into host cells such as *Zygosaccharomyces bailii* (see e.g. paragraph 0123) by means of electroporation of the nucleic acid [0117]. The procedures for purification of proteins from cell culture are well known in the art and a person of skill in the art at the time of filing of the instant invention as evidenced by the extensive references to procedures Gilbert et al provide in the paragraph 0126. It was well known in the art that electroporation of yeast is performed in the presence of monovalent ions and reducing agents (see e.g. Thompson et al. Yeast Vol. 14:565-571). Claim 5 is included in the rejection because any single nucleotide or dinucleotide or even greater combinations of nucleotides from pSB2 are identical to a nucleotide or dinucleotide or even greater number of nucleotides from the expression vector of Gilbert et al.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sjoberg (US 6,500,661; see entire document).

Sjoberg teaches the transformation of *Z. bailii* with recombinant GDP-fucose synthesizing enzymes (see bridging paragraph column 14-15). Following expression, the enzyme is purified (or recovered) (see column 18, line 35-54). Eukaryotic cells are

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transformed by electroporation (see column 18, line 35-41). It was well known in the art that electroporation of yeast is performed in the presence of monovalent ions and reducing agents (see e.g. Thompson et al. Yeast Vol. 14:565-571). Claim 5 is included in the rejection because any single nucleotide or dinucleotide or even greater combinations of nucleotides from pSB2 are identical to a nucleotide or dinucleotide or even greater number of nucleotides from the expression vector of Sjoberg.

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Conclusion

No Claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 18, 2004

Maria B Marvich, PhD
Examiner
Art Unit 1636


GERRY LEFFERS
PRIMARY EXAMINER